IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW [redacted]

DEFENDANT'S RESPONSE TO PLAINTIFFS' MOTION TO STRIKE DEFENDANT'S REPLY IN SUPPORT OF ITS EMERGENCY MOTION FOR STAY PENDING APPEAL

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Jazz's motion should be denied as an impermissible sur-reply filed under the pretense of a motion to strike. Despite filing two briefs, Jazz has not addressed two of the core issues with the injunction's bars on Avadel seeking FDA approval: that it (1) enjoins non-infringing activity (D.I. 671 at 4-5 and 7-9)[1]; and (2) violates Avadel's First Amendment rights (D.I. 671 at 9, 14). Instead of responding to those arguments, Jazz attempts to manufacture a procedural issue based on three purportedly new arguments, with respect to which Jazz's assertions are incorrect. Jazz's motion to strike should be denied, as there is no basis to strike or to file a sur-reply.

I. AVADEL ADDRESSED THAT LUMRYZ WAS A "PATENTED INVENTION"

Avadel's opening brief addressed the fact that LUMRYZ is a "patented invention" within the meaning of 35 U.S.C. § 271(e)(1). D.I. 671 at 1, 4-5, and 7-10. Specifically, Avadel argued "clinical studies fall comfortably within the safe harbor, which 'provides a wide berth for ***the use of patented drug*** in activities related to the federal regulatory process.'" D.I. 671 at 10 (emphasis added). Beyond that, the core premise of the injunction Jazz sought was that LUMRYZ was covered by the '782 patent, i.e., that LUMRYZ was the "patented invention." D.I. 666 at 2-3; *see also, e.g.*, D.I. 587 at 1 (Jazz asserting that "[c]laim 24 covers Lumryz as a whole; Lumryz cannot be sold without Jazz's invention."). Jazz cannot now do an about face and argue that LUMRYZ is somehow not the patented invention for purposes of the safe harbor. *Macfarlan v. Ivy Hill SNF, LLC*, 675 F.3d 266, 272 (3d Cir. 2012) (judicial estoppel "prevent[s] a litigant from asserting a position inconsistent with one . . . previously asserted in the same . . . proceeding").

The only other purportedly new argument Jazz identifies in this section is Avadel's discussion of the *Proveris* case Jazz identified in its opposition and the *Wesley Jessen* case addressing the same argument advanced by Jazz. D.I. 683 at 4-5 & n.1 (distinguishing *Proveris*

[1] "D.I." citations refer to docket entries in C.A. No. 21-691-GBW unless otherwise noted.

as addressing "a piece of laboratory equipment that was not subject to premarket approval," not a drug product requiring FDA approval and citing *Wesley Jessen* to rebut Jazz's assertion that LUMRYZ was no longer "subject to premarket regulatory approval"). Distinguishing a case and responding with new authority to arguments raised by the other party in its opposition is the essence of reply briefing and does not justify a motion to strike or a sur-reply.

II. AVADEL SHOWED THAT ITS CLINICAL TRIAL IS "REASONABLY RELATED" TO FDA APPROVAL

Avadel's opening brief also demonstrated that Avadel's use of LUMRYZ for clinical trials is "reasonably related" to an FDA submission seeking approval. D.I. 671 at 4-5, 7-10. Avadel explained that the safe harbor "categorically protects clinical trials, including all uses ***reasonably related*** to recruiting assistance for a clinical trial to support FDA approval." D.I. 671 at 8 (emphasis added). Jazz's assertion that Avadel presented "no evidence" to support this proposition is false. Avadel submitted a declaration from Jennifer Gudeman with its opening brief explaining that "The purpose of the REVITALYZ trial is to support Avadel's eventual application for the use of LUMRYZ to treat idiopathic hypersomnia." D.I. 672 at ¶ 4; *see also* ¶ 5 (explaining that the REVITALYZ patient count "was determined in order to … support FDA approval of LUMRYZ for the treatment of [IH]."). Moreover, Avadel cited the FDA website showing that FDA approved the trial for determining the suitability of LUMRYZ for IH, consistent with the goal of seeking FDA approval. D.I. 671 at 9. That evidence more than establishes the unremarkable proposition that Avadel's clinical trial is "reasonably related" to seeking FDA approval and within the safe harbor. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 n.6 (2005); *Nexell Therapeutics, Inc. v. AmCell Corp.*, 199 F. Supp. 2d 197, 203-05 (D. Del. 2002).

III. AVADEL TIMELY RAISED THE SAFE HARBOR ISSUE

Finally, Jazz complains that Avadel did not timely raise safe harbor as a "defense." Putting

aside the fact that Jazz's framing is wholly incorrect—the issue is not a defense but whether the injunction satisfies the dictates of Federal Rule of Civil Procedure 65 and other applicable law—the record belies Jazz's assertion. Jazz repeatedly took the position that it was not seeking to enjoin clinical trials in its complaint (C.A. No. 21-1594, D.I. 211 at ¶ 34, Prayer for Relief ¶ (D)); at the injunction hearing (D.I. 683, Ex. D at 101:5-6); and in its request for a "limited injunction" (D.I. 587 at 17). And when Avadel raised the safe harbor during the injunction hearing (D.I. 671, Ex. A at 64:15-21; 66:11-21; 79:11-21), Jazz did not suggest that Avadel had somehow waived the safe harbor, and instead said that it was not seeking to enjoin those activities. D.I. 683, Ex. D at 101:4-6. Jazz instead belatedly attempted to assert waiver for the first time in its opposition brief.

Jazz's argument that the infringement stipulation "does not carve out any of Avadel's IH activities," (D.I. 685 at 4), misstates the scope of the stipulation. The stipulation did not need to carve out Avadel's IH activities because the issue is not whether those activities infringe the patent under 35 U.S.C. § 271(a), which was the subject of the stipulation and concerns anyone who "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention." *See* D.I. 550. First, the stipulation has no bearing on the submission of an application to the FDA because it is none of those things. *See* D.I. 671 at 5-8. And, as to clinical trial activities, the issue is not whether those activities infringe under 35 U.S.C. § 271(a) but instead, as Avadel explained repeatedly at the hearing (and in its post-hearing submission), whether any use of LUMRYZ in clinical trials is excluded by statute from infringement under 271(e)(1). *See* 35 U.S.C. § 271(e)(2). The stipulation says nothing about the safe harbor or any submission by Avadel to FDA.

IV. CONCLUSION

This Court should deny Jazz's Motion to Strike and stay the injunction pending appeal.

Respectfully submitted,

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